

Remarks

Claims 1-5 and 7 are pending. Claims 1, 3 and 4 stand rejected. Claims 2, 5 and 7 have been indicated to be allowable if rewritten into independent form.

Claim 1 is directed to a drive assembly for an infusion pump which includes a barrel for holding a fluid reservoir and a rotating drive screw. Among other distinctive features, the barrel and the drive screw each have a respective longitudinal axis with “the screw axis displaced from and parallel to the barrel axis.” Such an arrangement is not taught or suggested by the prior art.

The Examiner generally states that Sams has some of the elements of claim 1, without linking specific claim language to specific parts of the reference. Rather, Figures 1-3 and “entire reference” are cited as being somewhat like some terms in claim 1.

Sams does explain with respect to Fig. 1 that:

“a fresh cartridge 17 containing fluid to be dispensed (for example, insulin) is placed in container 14, and the container is connected to the device 10 via the threaded connector 12 of member 21.” *Col. 7, lines 34-37.*

Looking at Fig. 1, this arrangement has a longitudinal axis which coincides with the central cylindrical axis of the device 10. And throughout Sams it is clear that it is rotation of the second member 22 which moves plunger 23. For example:

“A dose is set by winding the second member (22) ... the plunger (23) being thrust forwardly thereby to expel fluid from the container.” *The Abstract.*

Fig. 1 shows that the second member 22 is nestled concentrically within the outer shell 11 such that it also has a longitudinal axis which coincides with the central cylindrical axis of the device 10. Since Sams’ cartridge 14, container 17, and second member 22 all share a common longitudinal axis, there is no teaching or suggestion (nor any motivation) for an arrangement as required by claim 1 in which the screw axis is “displaced from and parallel to” the barrel axis (without regard to the particular component of Sams that the Examiner wishes to associate with the claimed “barrel”). Nor can Sams be analytically contorted so that either the first member 21 or plunger 23 might be viewed as equivalent to the rotating drive screw of claim 1, since neither

element in Sams rotates, that functionality is reserved for second element **22**. *See generally, entire reference.*

Moreover, for Sams to operate as intended, the second member **22** must be concentric with the device shell so that they share a common longitudinal axis such that there cannot be two different longitudinal axes as required by claim 1 which are “displaced from and parallel to” each other. For Sams also makes clear that:

“A dose setting sleeve (**53**) surrounds the second member and has threads (**54**) engaged with the device shell, the sleeve being coupled to the second member for rotation therewith. A dose is set by winding the second member (**22**) away from a fixed stop (**25**) until the sleeve (**53**) indicates the required dose amount ...” *The Abstract.*

To operate in such a manner, the second member **22** has to be concentrically disposed with the device (“barrel”). Any effort to modify this arrangement would impermissibly alter the fundamental principle of operation of Sams’ device in manner that would not be considered by one of ordinary skill in the art. See MPEP §2143.01 (“THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE.”)

Thus, the Sams reference neither anticipates nor makes obvious the drive assembly required by claim 1. Claims 2-5 and 7 depend from claim 1 and are allowable for the same reasons.

Conclusion

Applicants believe that no extension of time is required; however, this conditional petition is made to provide for the possibility that the applicants have inadvertently overlooked the need for an extension of time. If any additional fees are required for the timely consideration of this application, please charge deposit account number 19-4972.

It is submitted that all the claim rejections have been addressed and that all of the pending claims are now in a condition for allowance. Reconsideration of the application and issuance of a notice of allowance are respectfully requested. If the Examiner believes, after this amendment,

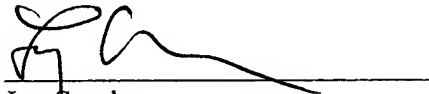
Application 10/037,614

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Response to Office action of September 12, 2005

that the application is not in condition for allowance, the Examiner is invited to call applicants' attorney at the telephone number listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jay Sandvos", is written over a horizontal line.

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